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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,431	01/03/2007	Gerhard Tivig	PHDE030358US	9506
38107	7590	03/31/2011	EXAMINER	
PHILIPS INTELLECTUAL PROPERTY & STANDARDS			BITAR, NANCY	
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BRIARCLIFF MANOR, NY 10510				
			ART UNIT	PAPER NUMBER
			2624	
			NOTIFICATION DATE	DELIVERY MODE
			03/31/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/595,431	Applicant(s) TIVIG ET AL.	
	Examiner NANCY BITAR	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/14/2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,12,14,16-18,20-22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,4,12,14,16-18,20-22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's response to the last Office Action, filed 9/14/2010, has been entered and made of record.
2. Claims 3, 4, 12, 14, 16-18, 20-22, 24-28 are currently pending.
3. Applicant's arguments filed 01/14/2010 have been fully considered but they are not persuasive.
4. Applicant argues that none of the display options noted by the examiner teach or fairly suggest displaying a histogram with a cumulative curve superimposed having common axes and common scales. Additionally applicant argues that neither Seely et al nor Zalenski et al nor the combination teaches displaying a cumulative curve superimposed on a histogram as the medical measurement is received.

In response, Seely teaches a method and apparatus (100) for providing continuous analysis and display of the variability of multiple patient parameters monitored by multiple bedside monitors (106a-106c) for each patient (102). Each monitor is connected to a patient interface and to a patient data storage unit (115) and a processor (113). Each monitored patient parameter is measured in real-time (i.e. as the medical measurement is received). Data artifacts are removed, and variability analysis is performed based upon a selected period of observation. Variability analysis yields variability of the patient parameters, which represents a degree to which the patient parameters fluctuate over time, to provide diagnostic information (see abstract). Seely teaches in figures 5 and 6A, 6B teaches displaying a histogram and the histogram is updated

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(paragraph[0085]). The Log-log Plot 520, 540 is simply a linear representation of the frequency distribution histogram 518, 538 on a log-log plot of frequency vs. variation. The straight-line distribution of points is characteristic of $1/f$ noise. The best fit of a straight line through the data points may be derived using standard linear regression analysis, and can also help inform the user respecting the appropriateness of this particular technique. The present invention calculates the slope of the line 522, 542 of the log-log plot and the x-intercept 524, 544. These values can be displayed as pairs of dynamic variability parameter histograms 526, 546. The slope is represented by one histogram 528, 548 and the intercept by another histogram 530, 550.

Examiner refers to the secondary reference Zaleski et al (US 2003/0101076). Zaleski teaches the cumulative curve being cumulative of the series of histogram wherein the model (expected) trajectories are compared with the measured (actual) trajectories of the patient. The comparison is evaluated to determine the degree of "likeness" or "sameness" between the expected and actual trajectories. Finally, by combining all trajectories together, it is possible to determine a cumulative estimate of "sameness" using a χ^2 -square test to show that the patient's cardiovascular parameters are either following or not following an expected path

(paragraph[0058-0059]). Zaleski teaches the use of graphical display that the physician maps pulls up data and request a plot or any other graph in order to have a real time assessment of the particular parameters in comparison to the historical record. Therefore the combination of Seely and Zaleski the cumulative curve been displayed as the medical image are being received. All remaining arguments are reliant on the aforementioned and addressed arguments and thus are considered to be wholly addressed herein.

Examiner Notes

5. Examiner cites particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that, in preparing responses, the applicant fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 3, 4, 12, 14, 16-18, 20-22, 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seely et al (US 2003/0117296) in view of Zaleski et al (2003/0101076).

As to claim 20, Seely et al teaches the method of automatically displaying medical measurement data in which a computer: receives the medical measurement data (107, figure 1) automatically converts in real time the received measurement data into data for a histogram including a updated in real time, (paragraph [0075], [0085]), during the conversion, generates a

cumulative curve indication of the medical measurement data the cumulative curve being cumulative of the series of histogram values (figure 5, and 6) and displays the histogram with the cumulative curve superimposed, the histogram and the cumulative curve having common axes and a common scales (paragraph [0088-0089]). While Seely et al. meets a number of the limitations of the claimed invention, as pointed out more fully above, Seely teaches the variability display (paragraph [0085-0090]) but fails to specifically teach the histogram includes an updates in real time values and generating a cumulative curve indicative of the medical measurement data the cumulative curve being cumulative of the series of histogram values. Specifically, Zaleski et al. teaches in FIG. 1, the system is implemented in computer hardware and software configured to operate on a dedicated software application and Web-enabled hardware computing system to access raw medical facts about patients extracted from lifetime clinical records and telemetry from available modalities (such as ventilators, pulse oximeters, ECG monitors, core temperature probes, etc.); and to convert this raw data into mathematical models for clinical outcome and real-time patient state prediction. Zaleski clearly teaches in figure 9 the model (expected) trajectories are compared with the measured (actual) trajectories of the patient. The comparison is evaluated to determine the degree of "likeness" or "sameness" between the expected and actual trajectories. Finally, by combining all trajectories together, it is possible to determine a cumulative estimate of "sameness" using a χ^2 -square test to show that the patient's cardiovascular parameters are either following or not following an expected path (see paragraph [0058-0060]) . It would have been obvious to one of ordinary skill in the art to generate in real-time the histogram data and the cumulative curve in Seely display in order to have an efficient system which is capable of acting as the foundation on which to establish

predictive methodologies for clinical application that would provide significant advantages in the process of defining a truly valuable decision support system for the clinician thus providing a convenient way to perform complex comparative trend analysis .Therefore, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention by applicant.

As to claim 3, Seely et al teaches a method as claimed in claim 5, further including: filing the histogram is filled with measurement data from a time window advancing in real time with selectable fixed length (see figure 6, note that for each patient parameter $v_{sub.k}$, a user, typically an attending physician, may select the number of data points $m_{sub.k}$ to collect in order to perform the variability analysis).

As to claim 4, Seely et al teaches a method as claimed in claim 20, wherein, during the conversion, the computer generates aids for the retrospective analysis of the histograms in the form of selectable functions that can be displayed on a viewing screen and outputs them together with the converted data combined as picture signals (note that the process 110 may be selected by a user from among a plurality of variability analysis options using a user interface 117, see paragraph [0061]).

The limitation of claim 12 has been addressed in claim 20 above..

Seely teaches the limitation of claim 14 wherein the retrospective analysis aids include a deviation readout (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set. This information can be updated continuously and displayed visually as a graph. Statistical

interpretation of the frequency distribution is dependent upon whether the distribution is normal or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards choosing an appropriate distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083]).

As to claim 16, Seely et al teaches the medical monitoring device as claimed in claim 28 further comprising an alarm indicator that is triggered measurement of histogram data is measured above or below a lower or upper alarm limits, (Alarms can be set so that if a variability histogram is within the normal range, it is displayed in one color (green, for example). If the value of the histogram rises above or falls below the normal range, it is displayed in a different color (red, for example), paragraph [0089]).

As to claim 17, Seely et al teaches the medical monitoring device as claimed in claim 28, wherein the histogram data is binned into histogram bins, the histogram bin size being definable by the user (The data is plotted in frequency bins, where each bin represents a proportional amount of variation, as measured by the squared difference from the mean, paragraph [0085]; see also Zaleski et al paragraph [0039-0040]).

As to claim 18, Seely et al teaches the medical monitoring device as claimed in claim 28 further comprising display means for displaying real-time signal patterns of the medical measurement data (real-time display, 502, figure 5; note that Zaleski teaches The ongoing results

of the analysis (e.g. the trend) may then be transmitted by Application Server 104 back to User Interface 105, such as in the form of a graphical display that is updated in real time; see paragraph [0050]).

As to claim 21, Seely teaches the retrospective analysis aids include at least one of: a cumulative curve cursor for determining a percentage of time that histogram values are below a current cumulative cursor position; range-selection cursors for determining a percentage of time that histogram values are within limits defined by the range-selection cursors; a variability/stability readout that provides information about variability of the measurement data; and a deviation and direction-change readout that shows deviation from a mean histogram value and a direction of measurement data change (The simplest method for computing variability parameters involves the calculation of mean and standard deviation of the frequency distribution of a selected data set. This information can be updated continuously and displayed visually as a graph. Statistical interpretation of the frequency distribution is dependent upon whether the distribution is normal or lognormal. There are standardized means of evaluating whether a distribution is accurately represented by a normal or log-normal curve, which include evaluation of kurtosis and skew. By calculating the kurtosis and skew, the user may be directed towards choosing an appropriate distribution. By evaluating the frequency distribution, the mean and standard deviation would represent the variability parameters for the particular patient parameter under evaluation, paragraph [0083]).

The limitation of claims 22 and 28 has been addressed above.

As to claims 24 and 26 and 27, Seely teaches the medical monitoring device as claimed in claim 12, wherein the histogram and the cumulative curve are displayed with common axes and scales (figure 5)

As to claim 25, Seely teaches the medical monitoring device as claimed in claim 28, wherein the histogram data includes a series of medical measurement values and the cumulative curve includes a sum of the medical measurement values (paragraph [0085]).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **NANCY BITAR** whose telephone number is (571)270-1041. The examiner can normally be reached on Mon-Fri (7:30a.m. to 5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikkram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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